K113763

MAR 16 2012

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510(k) SUMMARY

Nobles Medical Technologies II, Inc.'s SRM-Stitch™ 8F

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Nobles Medical Technologies II, Inc.
17080 Newhope St.
Fountain Valley, California 92708

Phone: (714) 427-0398
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Contact Person: Maria Hategan, Director of RA/QMS

Date Prepared: December 12, 2011

Name of Device and Name/Address of Sponsor

SRM-Stitch™ 8F

Nobles Medical Technologies II, Inc.
17080 Newhope St.
Fountain Valley, California 92708

Common or Usual Name

SRM-Stitch™ Vascular Suturing Device

Classification Name

Suture, Nonabsorbable, Synthetic, Polypropylene

Predicate Devices

SuperStitch® Vascular Suturing Device

Intended Use/Indications for Use

The SRM-Stitch™ 8F version is indicated for use in performing vascular stitching in general surgery, including endoscopic procedures. The SRM-Stitch™ 8F is not intended for blind vascular closure.

Technological Characteristics

The SRM-Stitch™ 8F version is hand-held and manually operated suturing devices designed to allow a physician to place a suture to a remote site either directly, through a cannula/introducer, or through a laparascopic access device. The device contains the following components and accessories: a suture delivery device, monofilament polypropylene suture, and a KwiKnot™ accessory. The optional KnotPusher™ accessory has been eliminated from current packaging configuration of SRM-Stitch™ 8F.

Substantial Equivalence

The SRM-Stitch™ 8F has the same intended use and indications for use, principles of operation, and fundamental technological characteristics as the cleared SuperStitch®, except that the SRM-Stitch™ 8F has a reconfigured suture sleeve and a refined guidewire port. The minor modifications to the SRM-Stitch™ do not raise any new questions of safety or effectiveness. Thus, the SRM-Stitch™ 8F is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 16 2012

Nobles Medical Technologies II, Inc.
% Ms. Maria Hategan
Director, of RA/QMS
17080 Newhope Street
Fountain Valley, California 92708

Re: K113763
Trade/Device Name: SRM-Stitch™ 8F, Vascular Suturing Device
SRM-Stitch™ 8F with guidewire, Vascular Suturing Device
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: Class II
Product Code: GAW
Dated: February 03, 2012
Received: February 15, 2012

Dear Ms. Hategan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113763

Indications for Use Statement

510(k) Number: _____
(if known)

Device Name: SRM-Stitch™ 8F, Vascular Suturing Device
SRM-Stitch™ 8F with guidewire, Vascular Suturing Device

Indications for Use: The SRM-Stitch™ 8F is indicated for use in performing vascular stitching in general surgery, including endoscopic procedures. The SRM-Stitch™ 8F is not intended for blind vascular closure.

Prescription Use __X___ OR Over-The-Counter Use_____
(Per 21 C.F.R. 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113763